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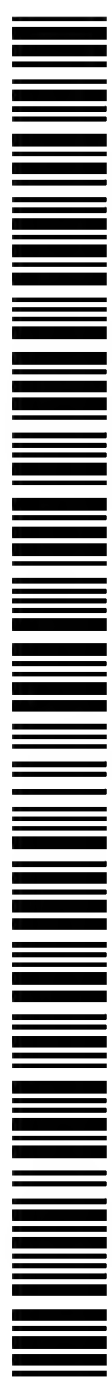
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- (74) Agent: **GRUBB, Philip**; Novartis AG, Corporate Intellectual Property, CH-4002 Basel (CH).
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- (71) Applicant (*for all designated States except AT, US*): **NOVARTIS AG** [CH/CH]; Lichtstrasse 35, CH-4056 Basel (CH).
- (71) Applicant (*for AT only*): **NOVARTIS PHARMA GMBH** [AT/AT]; Brunner Strasse 59, A-1230 Vienna (AT).
- (72) Inventors; and
- (75) Inventors/Applicants (*for US only*): **KOWALSKI, James** [US/US]; 70 Ketcham Road, Belle Mead, NJ 08502 (US). **PARTHIBAN, Lakshman, Jayanth** [US/US]; 215 Vista Drive, Cedar Knolls, NJ 07927 (US). **PATEL, Arun, P.** [US/US]; 10 East Maple Avenue, Succasunna, NJ 07876 (US).
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(54) Title: DIRECT COMPRESSION FORMULATION AND PROCESS

(57) Abstract: Dipeptidylpeptidase IV inhibitor (herein referred to as DPP-IV) that may be 98.5-100% pure is a high-dose drug capable of being directly compressed with specific excipients into solid form dosage forms, such as tablets and capsules having desired, hardness, disintegrating ability and acceptable dissolution characteristics. DPP-IV is not inherently compressible and thus presents formulation problems. Excipients used in the formulation enhance the flow and compaction properties of the drug and tableting mix. Optimal flow contributes to uniform die fill and weight control. The binder used ensures sufficient cohesive properties that allow DPP-IV to be compressed using the direct compression method. The tablets produced provide an acceptable *in vitro* dissolution profile.



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